

Sub A

WHAT IS CLAIMED IS:

1. An automated method for correcting mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) values in a blood, plasma, or sample containing a heme-colored interfering substance and analyzed on an automated hematology analyzer, comprising:
 - (a) dividing cellular hemoglobin concentration (gm/dL) by red blood cell concentration (cells/mm³);
 - (b) multiplying the value of (a) by a first constant to correct for differences in units of dimensions to obtain a corrected mean cell hemoglobin (MCH) value (gm/dL);
 - (c) dividing the cellular hemoglobin concentration by the hematocrit (HCT), (%), value; and
 - (d) multiplying the value of (c) by a second constant to correct for differences in units of dimensions to obtain a corrected mean cell hemoglobin concentration (MCHC) value (gm/dL).
2. The method according to claim 1, wherein the interfering substance in the blood sample is an extracellular hemoglobin product or an oxygen-carrying blood substitute.
3. The method according to claim 1, wherein the blood sample is a normal blood sample or an abnormal blood sample.
4. The method according to claim 1, wherein the sample is a plasma or serum sample.
5. The method according to claim 4, wherein the abnormal blood sample is derived from an individual having a pathological condition.
- 25 6. The method according to claim 5, wherein the pathological condition is selected from the group consisting of blood loss during surgery, blood loss during trauma, and hemorrhagic shock.

7. The method according to claim 2, wherein the extracellular hemoglobin product or the oxygen-carrying blood substitute is selected from the group consisting of recombinant human hemoglobin, cross-linked hemoglobin, polymerized, cross-linked hemoglobin, purified 5 bovine hemoglobin and hemoglobin coupled to polyethylene glycol (PEG-HGB).

8. The method according to claim 2, wherein the cell-free extracellular hemoglobin product is hemoglobin isolated and purified from human or animal blood.

10 9. A system for alerting a practitioner of the need to correct mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) values in a blood sample containing an exogenous blood substitute, and for correcting said values using an automated hematology analyzer, comprising:

15 a) labeling a blood collection container to indicate that the blood sample contained therein contains an exogenous blood substitute; and

b) correcting automatically for mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) values based on 20 the labeling indication of (a), wherein said correction is performed by the automated analyzer and comprises formula (1):

(1) MCH (corrected), (picograms/cell) =

25 Cellular hemoglobin (gm/dL) (x constant to correct for units of dimensions)
Red Blood Cell concentration (cells/mm³);

and formula (2):

(2) MCHC (corrected), (gm/dL) =

30 Cellular hemoglobin (gm/dL) (x constant to correct for units of dimensions
HCT (%));

wherein the corrected mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) values recover the original whole blood values for mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) in the analyzed blood sample.

5 10. The system according to claim 9, wherein the exogenous blood substitute is an oxygen-carrying hemoglobin substitute selected from the group consisting of recombinant human hemoglobin, cross-linked hemoglobin, polymerized, crosslinked hemoglobin, purified bovine hemoglobin and hemoglobin coupled to polyethylene glycol (PEG-HGB).

10 11. The system according to claim 10, wherein the exogenous blood substitute is hemoglobin isolated and purified from human or animal blood.

15 12. The system according to claim 9, wherein the labeling of the blood container comprises a sticker affixed to the container, said sticker being color-coded and/or bar-coded to indicate that the blood sample contained therein comprises an exogenous blood substitute.

20 13. The system according to claim 12, wherein the labeling comprises a bar code.

25 14. The system according to claim 9, wherein the constant to correct for units of dimensions in formula 1 is 10, and the constant to correct for units of dimensions in formula 2 is 100.

20 15. A method for automatic correction of interference to a blood chemistry value in a blood, plasma, or serum sample analyzed on an automated hematology analyzer, said interference due to the presence of an exogenous blood substitute in the blood, plasma, or serum sample, comprising:

25 a) labeling a sample collection container to indicate that the sample contained therein contains the exogenous blood substitute,

wherein said label signals correction of the blood chemistry value; and

5 b) correcting automatically the blood chemistry value based on the labeling signal of (a), wherein the correction is performed by the automated hematology analyzer employing the plasma hemoglobin value automatically generated by the automated hematology analyzer; and wherein the corrected blood chemistry value recovers the original whole blood chemistry result for the blood chemistry value in the analyzed blood sample.

16. A method for automatic correction of interference to a blood chemistry value in a blood, plasma, or serum sample, said interference due to the presence of an exogenous blood substitute in the sample, comprising:

10 a) labeling a sample collection container to indicate that the blood, plasma, or serum sample contained therein contains the exogenous blood substitute, wherein said label signals correction of the blood chemistry value; and

15 b) correcting automatically the blood chemistry value based on the labeling signal of (a), wherein the correction is performed by the automated analyzer employing the plasma hemoglobin value automatically generated by the analyzer; wherein the corrected chemistry value is determined by subtracting from the reported chemistry result the following product: (correction factor x plasma or serum hemoglobin value scaled to the appropriate units of dimensions of the reported analytes); and further wherein the corrected blood chemistry value recovers the original blood chemistry result for the blood chemistry value in the analyzed sample.

17. The method according to claim 15 or claim 16, wherein the exogenous blood substitute is an oxygen-carrying hemoglobin substitute selected from the group consisting of recombinant human hemoglobin, cross-linked hemoglobin, polymerized, crosslinked hemoglobin, purified bovine hemoglobin and hemoglobin coupled to polyethylene glycol (PEG-HGB).

18. The method according to claim 17, wherein the exogenous blood substitute is hemoglobin isolated and purified from human or animal blood.

19. The method according to claim 15 or claim 16, wherein
5 the labeling of the blood container comprises a sticker affixed to the container, said sticker being color-coded and/or bar-coded to indicate that the blood sample contained therein comprises an exogenous blood substitute.

20. The method according to claim 19, wherein the labeling
10 comprises a bar code.

21. The method according to claim 15 or claim 16, wherein the blood chemistry value is selected from albumin, alkaline phosphatase (ALP), alanine transaminase (ALT), amylase, aspartate transaminase (AST), urea, calcium, creatinine kinase (CK), bicarbonate, creatinine, creatinine
15 phosphokinase, muscle/brain (CKMB), total bilirubin, gamma glutamyl transferase (GGT), glucose, lactate dehydrogenase (LDH), magnesium, phosphate, lipase, mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC).

22. The method according to claim 21, wherein the blood
20 chemistry value is selected from albumin, alkaline phosphatase (ALP), amylase, calcium, bicarbonate, gamma glutamyl transferase (GGT), lactate dehydrogenase (LDH), mean cell hemoglobin (MCH), mean cell hemoglobin concentration (MCHC) and total bilirubin.

23. The method according to claim 15, wherein the
25 corrected chemistry value is determined by subtracting from the reported chemistry result the following product: (correction factor x plasma or serum hemoglobin value scaled to the appropriate units of dimensions of the reported analytes).

Color
98

623068 v1